

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:
Bodo KUKLINSKI *et al.*

Serial No.: 10/511,882

Filed: October 19, 2004

For: USE OF A MARE'S MILK CONCENTRATE
DRIED ON A HIGHLY-DISPERSED,
BIOLOGICALLY INERT MATRIX

Confirmation No. 6370

Group Art Unit: 1657

Examiner: Schuberg, Laura J.

Atty. Dkt. No.: SONN:057US

DECLARATION OF DR. NORBERT FUCHS

I, Norbert Fuchs, declare as follows:

1. I am an Austrian citizen, and my place of residence is Bruckdorf 135, Mariapfarr, Austria, A-5571.
2. I am an inventor of the above-referenced patent application. I am employed by Nutropia Ernährungsmedizinische Forschungs GmbH, which is the assignee of the above-reference patent application.
3. I am providing this declaration to present additional data showing that orally administering a mare's milk concentrate dried on a biologically inert, disperse matrix is therapeutically effective in treating human patients with neurodermatitis or psoriasis. The data are attached as Appendix 1.
4. The dried mare's milk concentrate used in the studies described below was formulated as described on page 19, line 7 to page 20, line 1 of the patent application. Following a baseline

examination, 1, 2, or 3 tablespoons (depending on the patient's age; *see* page 20 of the patent application for dosage details) of the dried mare's milk concentrate was administered to the patients once per day. Follow-up examinations were performed approximately one month, two months, and three months after the baseline examination. Patients were permitted to use greasing ointments and oil baths during the course of the study, but no other treatments of their neurodermatitis or psoriasis were permitted.

5. For the treatment of neurodermatitis (ND), the SCORAD (Severity Scoring of Atopic Dermatitis) index was used to qualitatively and quantitatively assess the degree of severity of the atopic eczema. As described on pages 22-23 of the patent application, SCORAD allows the standardized judgment of the degree of intensity of six typical morphologic changes (intensity), the portion of the affected skin area (%), and the subjective assessment of itching and sleep loss using a visual analog scale. The SCORAD index calculation uses the following formula $A/5 + 7B/2 + C$, where A = degree of expansion, B = intensity, and C = subjective symptoms. The SCORAD index has a range from 0-103. A SCORAD < 15 indicates mild ND, a SCORAD > 15 < 40 indicates moderate ND, and a SCORAD > 40 indicates severe ND.

6. Nine patients with moderate to severe ND were treated with the dried mare's milk composition as described in paragraph 4 above. As shown in the table and graph on page 4 of Appendix 1 the mean SCORAD decreased from a baseline of 34 to 22 at the first follow-up examination, 14 at the second follow-up examination, and 10.3 at the third follow-up examination. Improvement in SCORAD was evident in many of the patients by their first follow-up visit. By the third follow-up visit, eight of the nine patients had only mild ND

(SCORAD < 15). The only patient not to achieve a SCORAD < 15 still showed dramatic improvement from a SCORAD = 49 to a SCORAD = 17.

7. Photographs of two of the patients in the ND study described in paragraph 6 are provided on pages 5-13 in Appendix 1. Baseline photographs of patient MU were taken on May 27, 2002. Patient MU was photographed approximately two months later on July 22, 2002. Visual improvement in MU's ND is evident between the two sets of photographs. Baseline photographs of patient PC were taken on May 16, 2002. Patient PC was photographed approximately two months later on July 11, 2002. Visual improvement in PC's ND is evident between the two sets of photographs.

8. For the treatment of psoriasis, the Psoriasis Area and Severity Index (PASI) was used. This index takes into account the surface area of the affected skin as well as the extent of inflammation and excessive cell division. To this end, the investigator determines redness, thickening, and scaling for one focus each on the head, trunk, arms and legs, using a scale from 0 to 4. The counts are multiplied by an estimate of the total body area involved. From this calculation results a PASI of between 0 and 96.

9. Twelve patients with psoriasis were treated with the dried mare's milk composition as described in paragraph 4 above. The patients had baseline PASI scores of between 0.5 to 55.2. As shown in the table and graph on page 15 of Appendix 1, the mean PASI decreased from a baseline of 11.4 to 6.8 at the first follow-up examination, 4.3 at the second follow-up examination, and 3.8 at the third follow-up examination. Improvement was most dramatic in patients with the highest baseline PASI scores. For example, patient 12 improved from a baseline PASI = 55.2 to a PASI = to 3.2 at the third follow-up examination.

10. Photographs of two of the patients in the psoriasis study described in paragraph 9 are provided on pages 16-25 in Appendix 1. Baseline photographs of patient BM were taken on April 22, 2002. Patient BM was photographed again on August 1, 2002. Visual improvement in BM's psoriasis is evident between the two sets of photographs. Baseline photographs of patient HR were taken on April 25, 2002. Patient HR was photographed again on July 25, 2002. Visual improvement in HR's psoriasis is evident between the two sets of photographs.

11.I declare that all statements made of my knowledge are true and all statements made on the information are believed to be true; and, further that these statements were made with knowledge that willful false statements and the like so made are punishable by fine or imprisonment or both, under § 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of this application or any patent issued thereupon.

Date:

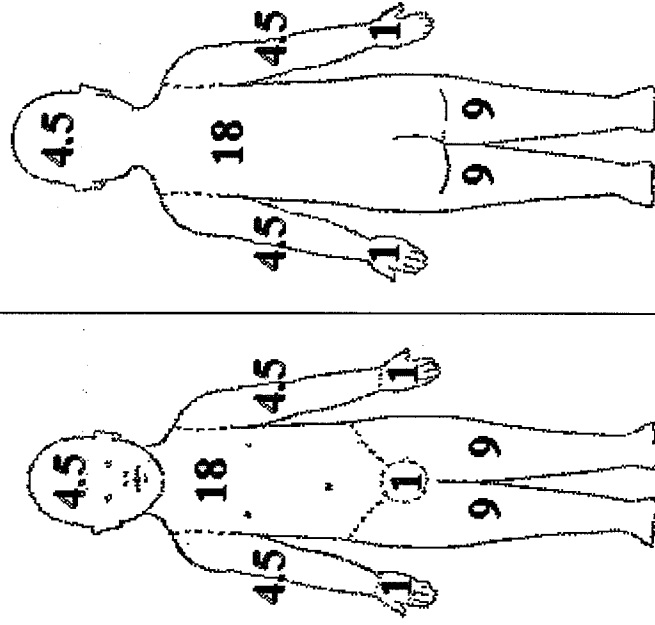
July 16 / 2008


Dr. Norbert Fuchs

APPENDIX 1

target parameters

SCORAD



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Severity Scoring of Atopic Dermatitis:

Assessed are: the degree of six typical morphological changes (intensity), the portion of the affected Surface of the skin (%), the subjective perception of pruritus, and sleep loss based on a visual analog scale, as well as the total score.

SCORAD – Index calculation

A = degree of expansion

B = intensity

C = subjective symptoms

$$\text{SCORAD} = A/5 + 7 \times B/2 + C$$

Intensity is assessed to be most important.

SCORAD - Index

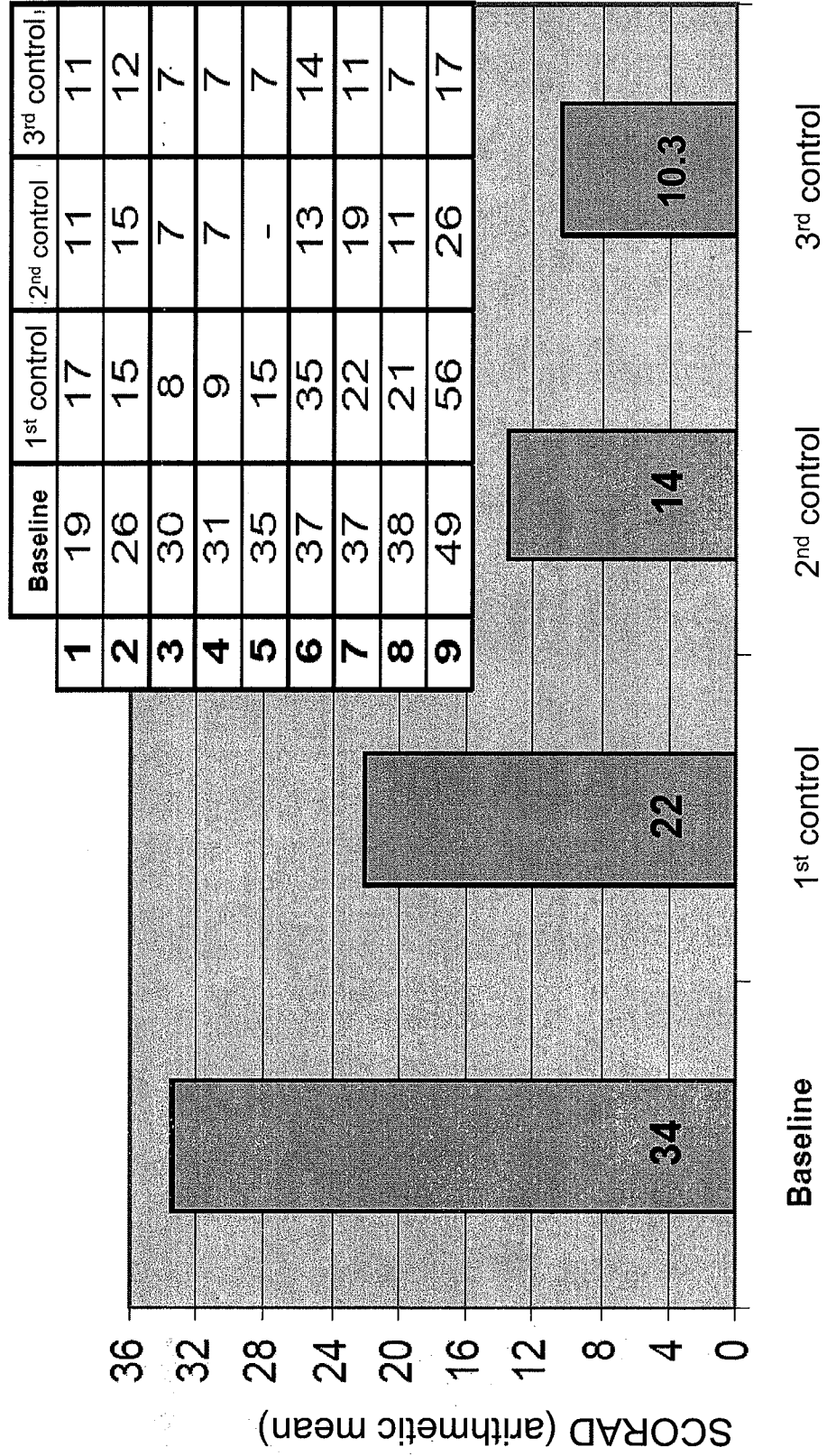
0 – 103 possible

mild ND = SCORAD < 15

medium/moderate ND = SCORAD > 15 < 40

severe ND = SCORAD > 40

neurodermatitis (n=9)

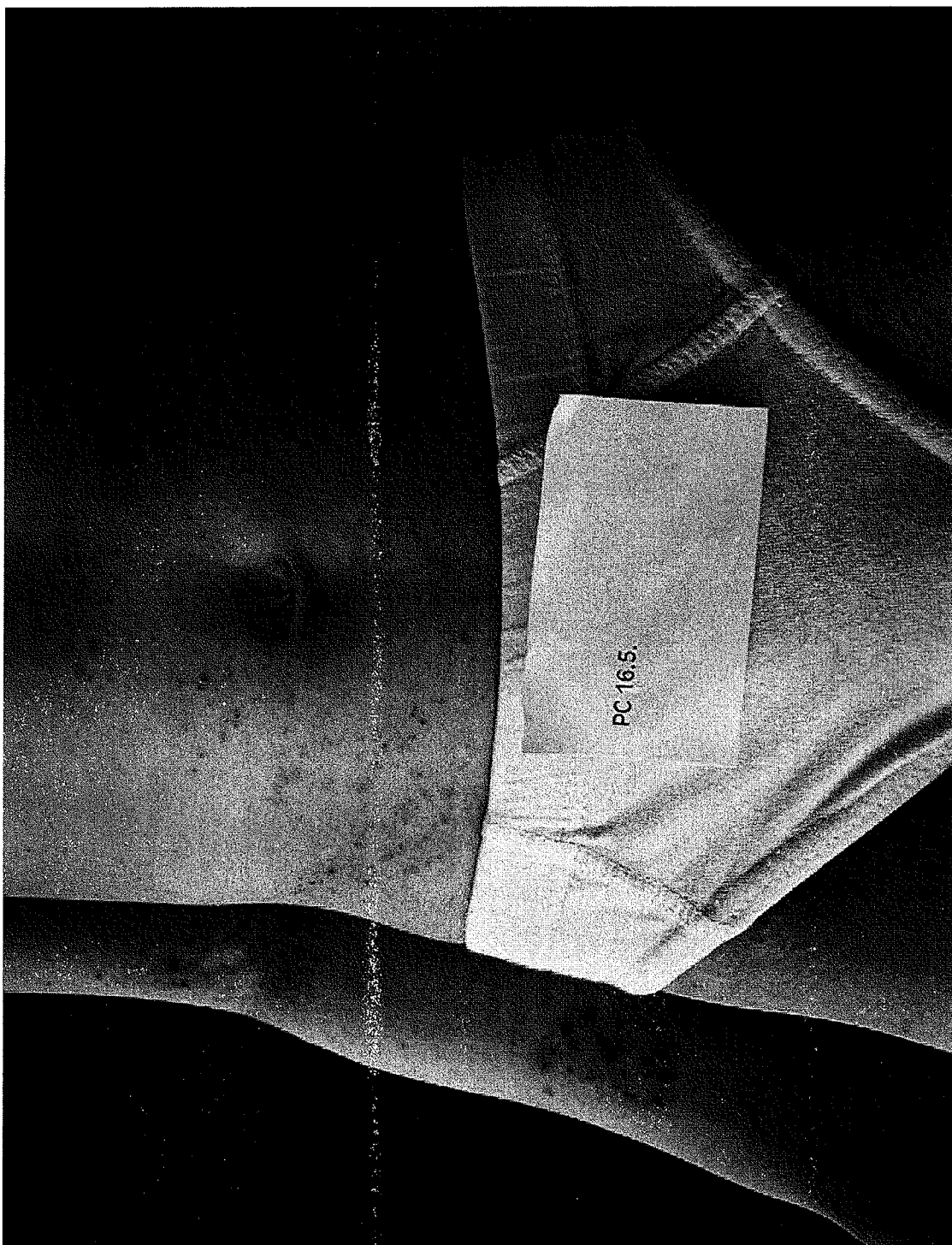






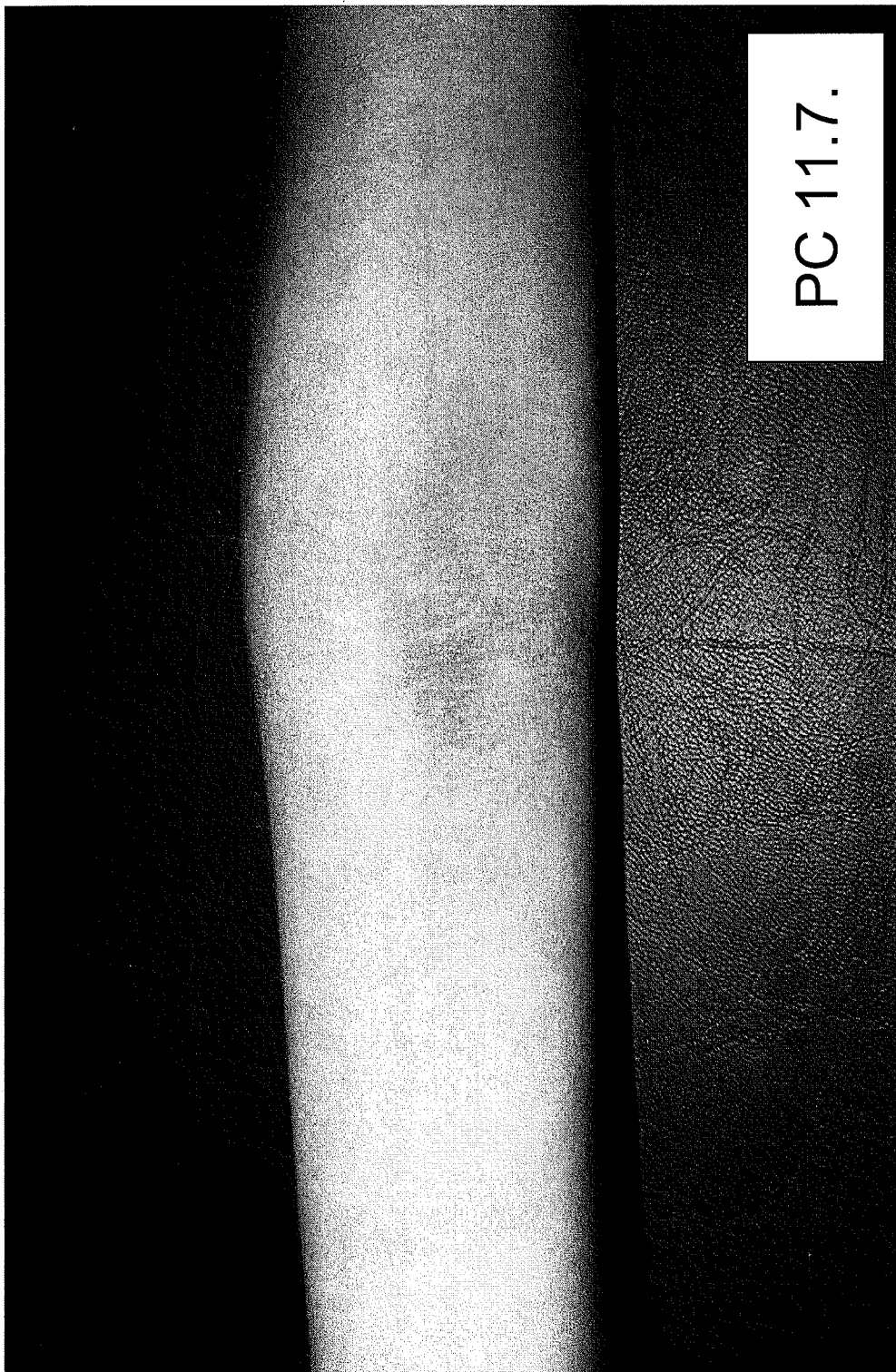
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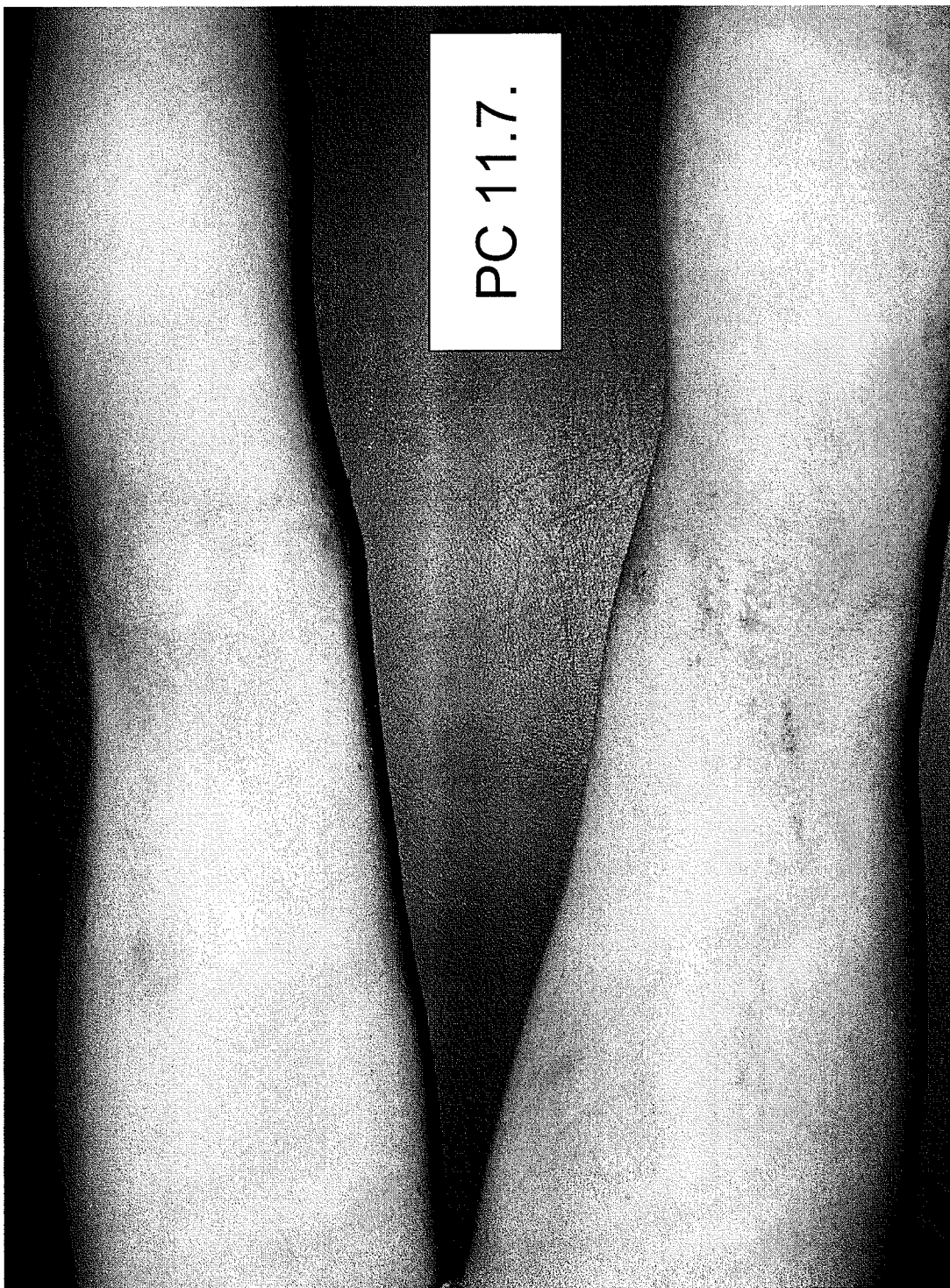












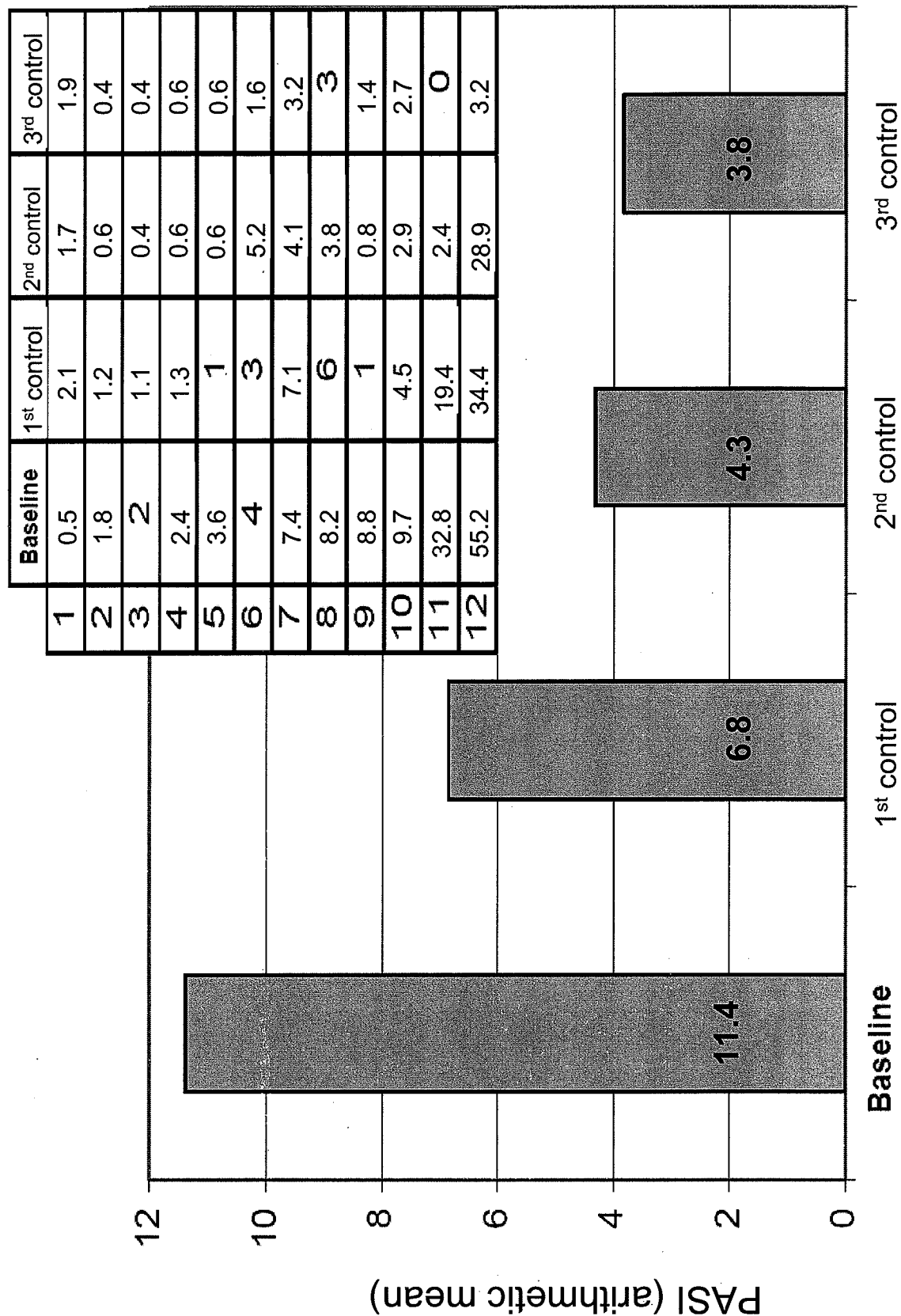
psoriasis

Primary parameter: PASI INDEX

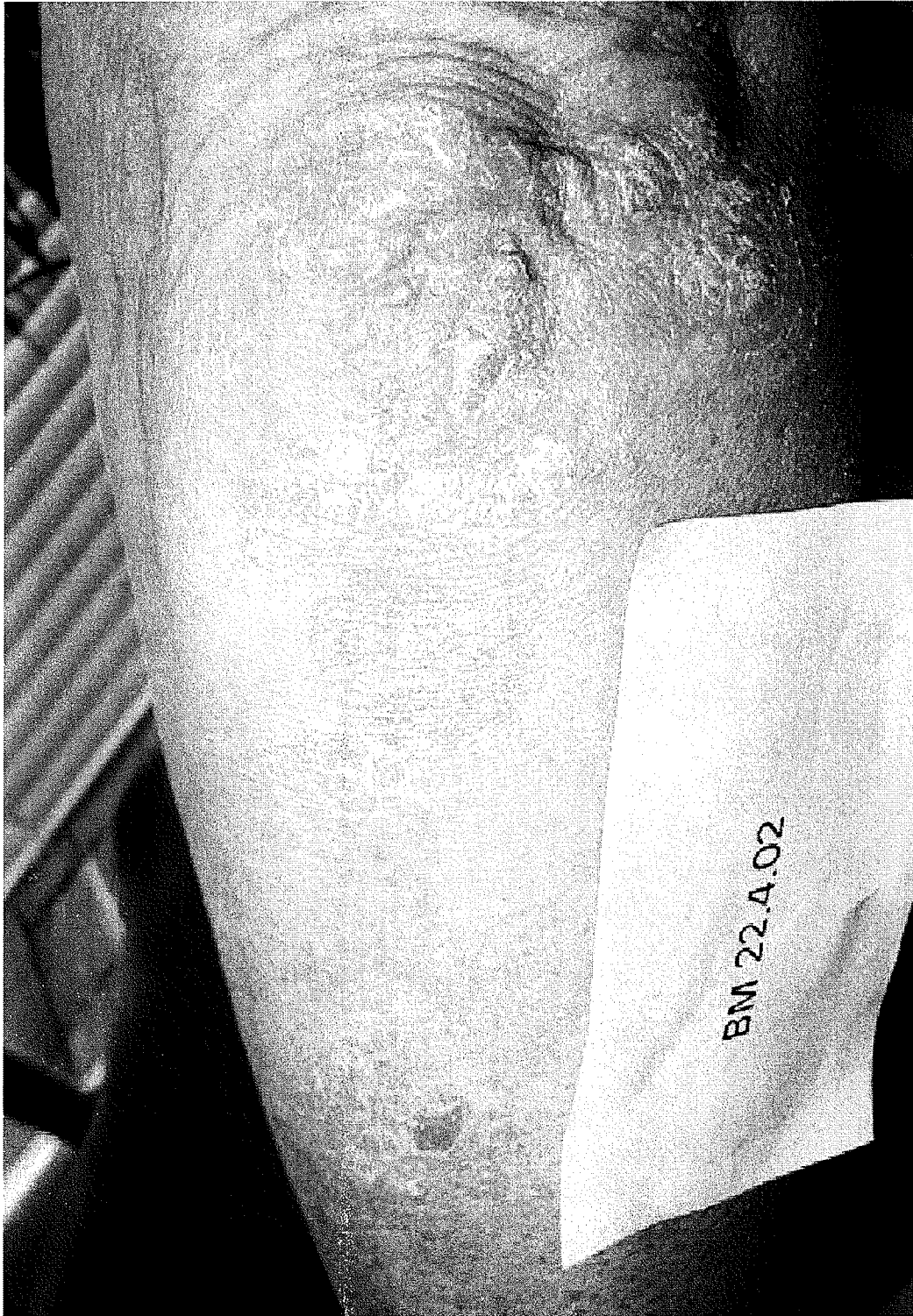
Psoriasis Area and Severity Index

Degree of expansion and intensity of typical morphological changes of the surface of the skin are assessed. The body is divided up into 4 sections (legs, trunk, arms, head), the point score additionally reflects intensity of the parameters pruritus, reddening (erythema), skin scales and thickness of the skin.

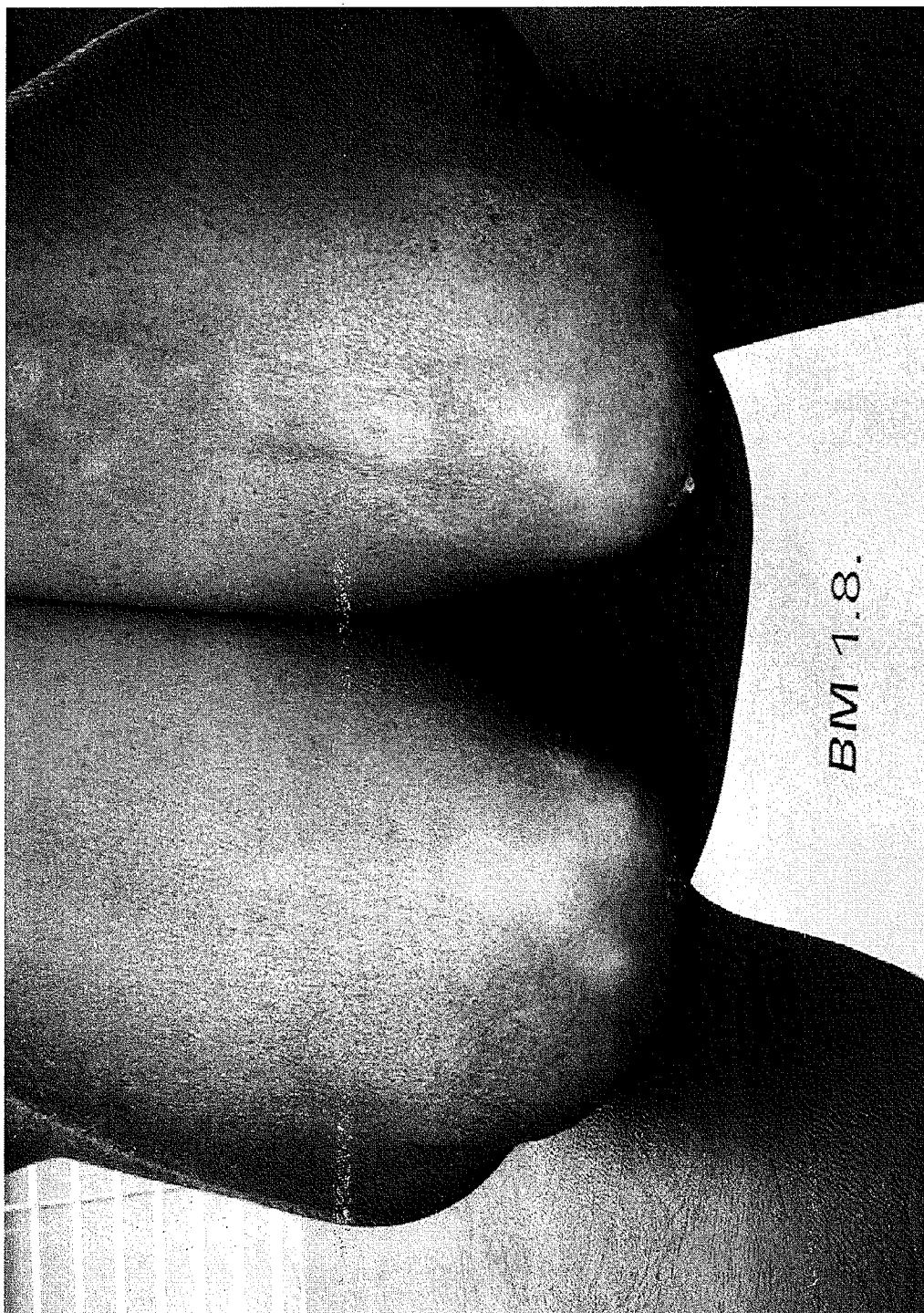
psoriasis (n=12)













HR 25.4.

